

REMARKS

Applicants submit these remarks in response to the Office Action dated June 1, 2006. Applicants elected Group I, claims 1-5, in the reply filed on 13 April 2006. Claims 6-17 have been withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-5 are under examination.

35 USC § 112, first paragraph

Claims 2 and 3 were rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. The claims contain subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, possession of the claimed invention.

According to the Examiner, there is no teaching regarding the relationship of structure to function, and the claims therefore encompass a genus of molecules, which vary substantially in composition and could have very different structural and functional characteristics from polypeptide that applicants have disclosed.

The Examiner cited *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, for the proposition that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (*Vas-Cath*, page 1117.) *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016, were also cited, as was *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483.

Applicants cite to the recent Federal Circuit decision *Falkner v. Inglis*, Slip Op. 05-1324 (May 26, 2006) which clarified the written description law as it pertains to biological molecules. The court held that,

(1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves

a biological macromolecule must contain a recitation of known structure.

The court further stated that recitation of known structure is not required, citing *Capon v. Eshlar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) and distinguishing *Eli Lilly*. The court also noted that “the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.” (*Falkner*, Slip. Op. at 17).

The Examiner concluded that “only an isolated complex comprising sclerostin and noggin, or sclerostin and chordin, but not the full scope of the claimed complexes comprising a first and a second TGF- β binding protein in a specific association, is adequately described in the disclosure.” (Office Action, pages 4-5.)

Applicants respectfully disagree on the grounds that the class of TGF- β binding proteins is known in the art, and under *Falkner*, the application need not disclose the chemical structures. However, without acquiescing to the ground of rejection, applicants have cancelled claims 2 and 3 and amended claims 4 and 5 as independent claims no longer dependent on claim 3.

Claims 2 and 3 are further rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for an isolated complex comprising sclerostin and noggin, or comprising sclerostin and chord in, allegedly does not provide enablement for other isolated complexes comprising other TGF- β binding proteins.

Without acquiescing to the ground of rejection, applicants have cancelled claims 2 and 3 and amended claims 4 and 5 as independent claims no longer dependent on claim 3.

Reconsideration and withdrawal of this rejection are respectfully requested.

35 USC §112, second paragraph

Claims 1-5 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 allegedly are indefinite for the recitation of “in specific association.” It is allegedly unclear what specific association the claims intend to encompass. Claims 4 and 5 were rejected for depending upon a rejected claim.

The term "specific association" is used in the specification to describe the formation of a complex between sclerostin and either chordin or noggin. Mixtures of DAN, noggin, chordin, and other proteins including BMP receptor Fc-fusion proteins were injected over sensor chips to which sclerostin was bound. The specificity of binding ("association") was demonstrated by the binding of non-degraded (full-length) chordin and noggin to sclerostin (page 57, line 14 to page 58, line 9).

Applicants submit that the term is not indefinite and has clear meaning from its contextual use in the specification. That use itself is consistent with the search for protein partners that will specifically associate to carry out biological activities, such as that described at page 58, lines 10-15 in which chordin blocked induction of phosphatase by BMP-6, and noggin was detected in immuno precipitates using an anti-sclerostin antibody, signaling the "specific association" of noggin (as distinguished from proteins in general) with sclerostin.

Reconsideration and withdrawal of this rejection are respectfully requested.

35 USC §102(b)

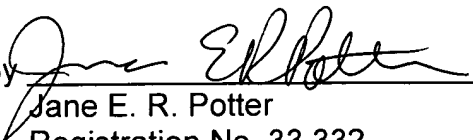
Claim 2 is rejected under 35 U.S.C. §102(b) as being anticipated by Grainger et al. Patent No: 6,117,911. Allegedly, the '911 patent teaches a complex comprising a first and second TGF- β binding proteins, the latency associated peptide (LAP) and the TGF- β binding protein (LTBP-1). Without acquiescing to the ground of rejection, applicants request withdrawal of the rejection in view of the cancellation of claim 2.

If fees are believed necessary, the Commissioner is authorized to charge any required fee, deficiency or credit any overpayment to Deposit Account No. 04-0258. A duplicate copy of this document is enclosed.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

Respectfully submitted,
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